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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,583

05/11/2005

Takahide Kishimoto

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06/02/2006

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EXAMINER

MEAH, MOHAMMAD Y

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/534,583	Applicant(s) KISHIMOTO ET AL.	
	Examiner Mohammad Meah	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,20,25,27 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,20,25,27 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/11/05</u> <i>6/11/05</i> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

DETAILED ACTION

Applicant, on date 3/24/2006 elected with traverse Group X (claims 18, 20, 25, 27 and 31) for examination.

Election/Restriction

Applicant, on date 3/24/2006 elected with traverse Group X (claims 18, 20, 25, 27 and 31) drawn to modified sarcosine oxidase that has lower action to proline. Groups I-IX and XI-XXI (claims 1-17, 19, 21-24, 26, 28-30 and 32-42) of election/restriction-office action of date 12/29/2005 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

The traversal is on the ground(s) that Groups I-IX and XI-XXI (claims 1-17, 19, 21-24, 26, 28-30 and 32-42) are linked through generic claims such as claims 1, 3, 18, 20, 35 and 42 and restriction of claims derived from a generic claim is not proper. However, claims 1, 3, 35 and 42 are not generic to the elected claims at all. Claim 18 and 20 herein do link inventions X- XI, but restrictions as presented is proper subject to the non-allowance of the linking claims. Applicant should note however that claims 18 and 20 do not link the elected group to groups I-IX and XII-XXI, as these claims are not generic to the subject matters of the elected group. Moreover modified sarcosine oxidases and DNAs encoding them are different substances having different functions. Furthermore each of the modified sarcosine oxidase having various amino acid

Art Unit: 1652

residues modified also has its own unique structure and function. The specification does not identify any common feature of all of these modified sarcosine oxidase which are disclosed as essential to the common utility. Applicants further argue that there would be no undue burden on the examiner to examine claims directed to groups I-XXI. This is not persuasive because while the search for each of these distinct groups would be overlapping it would not be coextensive. Art that applies for sarcosine oxidase and DNA encoding them may or may not be relevant to the others. Therefore the restriction is maintained and FINAL.

Claim Rejections

35 U.S.C 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1652

Claims 18, 20, 25 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of modified sarcosine oxidase having low proline activity wherein at least one amino acid residue of any sarcosine oxidase or of sarcosine oxidase having 50% sequence identity with SEQ ID NO:1 is modified or any sarcosine oxidase having the amino acid residue position corresponding to positions 89, 94 or 322 of SEQ ID NO:1 modified. The specification teaches the structure of only a few representative species of such variants each with only a small number of altered amino acids compared to the parent modified sarcosine oxidase. However, the currently claimed genus includes modified sarcosine oxidase with any number of alterations of the parent enzyme as long as sarcosine oxidase activity is maintained and low proline activity produced. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of having sarcosine oxidase having low proline activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a

Art Unit: 1652

skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 18 , 20, 25 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for modified sarcosine oxidase having low proline activity wherein said variant consist of substitution of the residue 94 of SEQ ID NO: 1, does not reasonably provide enablement for any variant of any parent sarcosine oxidase wherein said variant has modified sarcosine oxidase activity and comprises of one or more mutations selected from the group consisting of substitution of the residue equivalent to 89, 94 and 322 of SEQ ID NO:1 with any amino acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 18, 20, 25 and 31 are so broad as to encompass any sarcosine oxidase wherein said variant has modified sarcosine oxidase activity and comprises of one or more mutations selected from the group consisting of a substitution of the residue corresponding to 89, 94 and 322 position of SEQ ID NO: 1. Thus, the currently claimed genus includes sarcosine oxidase with any number of alterations of the parent enzyme as long as sarcosine activity is maintained and low proline activity produced. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of sarcosine oxidase broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and

Art Unit: 1652

functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to only a few representative species of such modified sarcosine oxidase each with only a small number of altered amino acids compared to the parent sarcosine oxidase.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any because the specification does not establish: (A) regions of the protein structure which may be multiply modified without effecting sarcosine oxidase activity; (B) a rational and predictable scheme for major modifications to any sarcosine oxidase at large numbers of residues with an expectation of obtaining the desired biological

Art Unit: 1652

function; and (C) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of any sarcosine oxidase wherein said variant has modified sarcosine oxidase activity and comprises of one or more mutations selected from the group consisting of mutation of the residue corresponding to 89, 94 and 322 residue of SEQ ID NO:1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of sarcosine oxidase having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

CLAIM Rejection - 35 U.S.C 102

35 U.S.C 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1652

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 18, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshiaki et al. (JP 10248572) and Yoshiaki et al. (Febs letter 1998, 48, 263-266)

Yoshiaki et al. (JP 10248572) teach a modified sarcosine oxidase having F345 is modified to either of F345A, F345G, F345V or F345 and which shows low reactivity to L-proline compare to the unmodified sarcosine oxidase.

Yoshiaki et al. (FEBs letter 1998, 48, 263-266) teach a recombinant sarcosine oxidase which at 37 ° C and pH 8.0 shows less than 0.7% (0.15%) activity to proline compared to 100% sarcosine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed M. Y. Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The

Art Unit: 1652

fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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